

KA2 Addendum In-Situ Visit

PROJECT INFORMATION

FINANCING AGREEMENT NUMBER	825812
FULL PROJECT TITLE	Cross-regional coordination for rapid and deep adoption of personalized healthcare
PROJECT ACRONYM	Regions4PerMed
FINANCING SCHEME	CSA
STARTING THE PROJECT	01/11/2018
DURATION	54 months
CONNECTION ID	H2020-SC1-2018-Single Stage-RTD
PROJECT WEBSITE	http://www.regions4permed.eu/

INFORMATION PROVIDED

TITLE	KA2 Addendum In-Situ Visit
WP LEADER	UMWD
COOPERATION PARTNERS	All
NATURE	Report
AUTHOR	Aldona Iwasieczko, UMWD
ASSOCIATES	Gianni D'Errico (TLS), Claudia Mariut (TLS), Letizia Pontoriero (TLS), all partners
REVIEWERS	Partners, Speakers



Content

Content	2
List of abbreviations	3
1 Purpose of the site visit	4
2 Agenda of the in-situ visit	6
3 Summary of the visit.....	8
Wrocław Technology Park SA	8
BIOTTS S.A	11
WPD Pharmaceuticals Ltd.	11
VASA THERAPEUTICS Ltd.....	12
AMPLICON Ltd.	12
Regions4PerMed network dinner	12
Clinical Research Center of the Medical University of Wrocław	16
GLUCOACTIV Ltd.	17
MultiMedic POINT.....	18
4 Conclusions.....	19
Appendix A Site visit by participants.....	20
Appendix B Participant Feedback - Survey.....	22



List of abbreviations

PH	Personalised Health
PM	Personalised Medicine
KA	Key thematic Area
R&D	Research and development
SMEs	Small and medium companies
WPT	Wrocław Technology Park SA
OBK	Clinical Research Centre
OFW	Early Phases Center
UMW	Wrocław Medical University
JOB	Business Environment Unit
IT	Information technology
SME	Small-Medium Enterprises?
HACCP System	Hazard Analysis and Critical Control Points
GMP	Good Manufacturing Practice
GHP	Good Hygiene practice
THT	Through-Hole Technology
SMT	Surface Mounting Technology
UPS	Uninterruptible power supply
CVD	Cardiovascular diseases
PAD	Peripheral diseases
CRO	Contract research implementation
API	Active Pharmaceutical ingredients
DP	Medicinal products
ATMP	Advanced Therapy Medicine products
CTA	Clinical trial application
CTR	Clinical Trials Regulation
GBM	glioblastoma multiforme
CED	convection-assisted drug delivery
ADC	antibody-drug conjugate
CTR	Clinical Trials Regulation
MRI	Magnetic Resonance Imaging
HTA	health technology assessment
ARO	Academic Research Organization



1 Purpose of the site visit

The leading goal of the Regions4PerMed project is to intensify activities in the area of interregional coordination, for the use in the field of personalised medicine (PM) and personalized health (PH) in European regions, to increase the involvement of regional authorities, researchers, decision makers in the implementation of PM and PH. Another objective is to establish possible inter-regional cooperation in risk management, align strategies and financial instruments, identify key investment areas and publish a European Regional Program to support the provision of PM and PH in European regions. The project is aimed at supporting the coordination of regional innovation policies and programs in the areas of PM and PH, establishing a permanent dialogue between European regions and enabling the creation of interregional joint investments under PM and PH.

With the project goals in mind, Regions4PerMed initiated a process of dialogue, exchange of experiences and stakeholder engagement in five thematically focused key areas (KA) to inform relevant regional stakeholders about the opportunities and needs of PM and PH. Each of the five Regions4PerMed regional partner organization is responsible for one specific KA, namely: "Big data, electronic health records and health management" (KA1), "Health technology in connected and integrated care"(KA2), "Personalizing the medical industry"(KA3), "Innovation flow in care health"(KA4) and "Ethical and socio-economic aspects"(KA5).

Exchange of experiences, indication of problems of Regions4PerMed stakeholders is conducted in the form of a series of interactive events. These include a technical conference highlighting the salient aspects of relevant KAs, followed by a workshop and co-creation meeting.

To ensure that Regions4PerMed partners have a full, more hands-on understanding of the topics discussed, it is planned that the workshop will be accompanied by an in-situ visit of regional high-level organizations that contribute to the field of PM and PH. They outline their PM and PH approaches to the respective KAs on site, ensuring that participating partners have a full understanding of the KAs as well as offering the opportunity for in-depth exchanges with regional stakeholders.

Due to the Covid-19 pandemic, most of the Regions4PerMed events have changed the setup of meetings from assumed interactive in-person events to virtual meetings. Therefore, in-situ visits in most cases could not take place in person during the events described above but had to take place virtually or be postponed.

The consortium decided that the site visit in the region of Lower Silesia will be carried out at the beginning of 2023, which will allow for a full presentation of the specifics of the approach to PM and PH in the region.

The in-situ visit was divided into two areas:

- a) As part of the first area on February 2, 2023. Wrocław Technology Park S.A. (WTP) and entities operating within WTP, whose activities clearly fit into the area of PM (PM), were presented.
- b) As part of the second area, the Clinical Research Center (OBK) and the Early Phases Center (OFW) operating as part of the Medical University of Wrocław (WMU) and entities whose activities were focused on the area of personalized health (PH) were presented on the day.

During the in-situ visit on February 2, 2023, the focus was on the presentation of the business environment unit – WTP as an entity supporting various forms of entrepreneurship in the Lower Silesia



region, which are a carrier of the region's development, but also using the scientific potential, know-how and creativity of people working in them. It is an organization with a long tradition and reputation, bringing together entities visible in the region focused on creating new solutions in the field of PM, many of which belong to or are related in various ways to the broad subject of healthcare. The Lower Silesian PM and PH ecosystem is characterized by a strong academic and scientific base and a growing number of SMEs, as well as a certain representation of large pharmaceutical companies, such as Captor Therapeutics SA, which is a biopharmaceutical company specializing in the development of drugs that cause targeted protein degradation. Operating in the area of cancer and autoimmune diseases, for which there is currently no treatment, or the available methods have significant therapeutic limitations. In Wrocław, the heart of Lower Silesia, Captor Therapeutics SA located modern and well-equipped laboratories. Knowledge in the field of biological and chemical sciences, integrated with diverse competences and extensive experience of employees, enable the company to carry out all early stages of drug development. Another biopharmaceutical company is Pure Biologics SA focused on discovering and developing biological drugs and developing extracorporeal therapies. We operate in the field of immunology, autoimmunity, and neurological rare diseases, conducting research using our own technological platforms for the selection of active particles – antibodies and aptamers. Offering commercial cooperation in several areas, including early stages of development of biological drugs, selection and characterization of antibodies and aptamers, as well as production, purification and analysis of proteins.

Among the presented entities of this WPT ecosystem, there are entities whose activities clearly fit into the area of PM (PM):

WPD Pharmaceuticals Ltd – a Polish biotechnology company focusing on the development of biological and chemical molecules involved in targeted therapy for brain glioma and other tumors of the central nervous system.

BIOTSS SA – a Polish biotechnology company developing proprietary carriers and drug formulas in the field of oncology and diabetology.

VASA THERAPEUTICS Ltd. – a privately held biotech company committed to discovering and developing best-in-class drugs for the treatment of heart, peripheral arterial disease, scarring and other vascular diseases.

AMPLICON Ltd. – a Polish company from the biotechnology industry, focused on genetic tests detecting celiac disease – celiac disease, caffeine or folic acid metabolism disorders, fructose and lactose intolerance, tendency to overweight, as well as sports predispositions. Conducting DNA tests for breast or ovarian cancer. Offering diagnostic sets of the AmpliTest and AmpliSNiP series, which enable the diagnosis of infectious diseases – both viral and bacterial, as well as parasitic, enabling the analysis of mutations or polymorphisms.

During the in-situ visit on February 3, 2023, the focus was on the presentation of the Clinical Research Center of the Medical University of Wrocław.

Clinical Research Center of the Medical University in Wrocław (UMW)

Early Phases Center (OFW)

Among the presented entities of this ecosystem of the Medical University, whose activities clearly fit into the area of PM, there were.:



GLUCOACTIV Ltd. - a Polish company that creates solutions in the field of modern medicine, focusing on non-invasive measurement of not only blood glucose, but also other substances such as cholesterol, hemoglobin, hydration and many others. Involved in innovative investments and breakthrough technologies in the healthcare industry.

MultiMedic POINT - a technology company that provides consulting and design services in the field of IT. Specializing in providing telemedicine solutions. With many years of experience and ready solutions in the field of telecare and telemedicine.



Photo 1: Regions4PerMed - Medical University in Wrocław

2 Agenda of the in-situ visit

February 01, 2023

7:00 p.m. Networking Dinner (Consortium Members)

02. February 2023

10:00 am On site visit of Wrocław Technology Park SA is a business environment institution that supports companies operating on every scale, the largest technology park in Poland. Welcome greeted by the President of the Wrocław Technology Park and the Representatives of Marshal's Office of Lower Silesia

10:10 am Presentation of projects implemented by the Wrocław Technology Park and the research and development facilities of the Wrocław Technology Park.

10:40 am Presentation of WPD Pharmaceuticals Ltd. operating in Wrocław Technology Park in the field of research and development in the field of PM .

11:00 am Study visit to Wrocław Technology Park Delta laboratories.

12:00 am Presentation of BIOTTS SA operating in WTP in the field of research and development in the field of PM .



- 12:20 am** Presentation of VASA THERAPEUTICS Ltd. operating in WTP in the field of research and development in the field of PM .
- 12:40 am** Presentation of AMPLICON Ltd. operating in WTP in the field of research and development in the field of PM .
- 2:00 pm** Short Tour of Wroclaw Technology Park combined with the presentation. Study visit to the Clean Room Laboratory of the WPT and the Experimental Department (supercritical extractor). Presentation of the laboratory infrastructure of the Park's residents.
- 7:00 pm** Networking Dinner (Consortium Members, invited Guests)

03. February 2023

- 10:30 am** On site visit of Early Phase Center at University Clinical Research Support Center
- 11:00 am** Presentation of the Multi Medic Point on Diabetes care in action, operating in the field of research and development in the field of PM
- 11:30 am** Presentation of the GLUCO ACTIVE Ltd. operating in the field of research and development in the field of PM
- 1:30 pm** Presentation of several clinical trials conducted by the University Clinical Research Support Center.



3 Summary of the visit

Wrocław Technology Park SA

Business Environment Unit (JOB) - an entity supporting various forms of entrepreneurship in the Lower Silesian region, which are a carrier of the region's development, but also using the scientific potential, know-how and creativity of people working in them. JOB not only provides space for development and activities aimed at, among others, PM, it also creates a community of entrepreneurial people. It is the largest Technology Park in Poland in terms of the number of companies operating in its area. Their diversity proves that WPT's offer is adapted to the needs of various types of business, operating on any scale. It is home to innovative companies, entrepreneurs and scientists from the research and development sector, as well as companies locating their research and development departments here. Both start-ups, enterprises from the SME sector, as well as large international companies whose activities, e.g. they are directed to the PM and PH area. WPT is an institution where companies with various business profiles, operating in many market sectors, can develop. At any given moment in their development, they can take advantage of the support they need. It can only be the rental of office space tailored to the needs of the company, or the use of many specialized laboratories and prototype workshops. However, cooperation with the WPT may be broader. Companies that start their activity in the business incubator can, at the same time, or after some time of functioning on the market, start using the WPT laboratories, research and development services or support in the field of obtaining subsidies. After the end of the incubation period, they can continue their activities at WTP, renting office or laboratory space to create their own studio. WPT's offer includes business products and services, focused around 9 areas presenting a full spectrum of activity - from renting business infrastructure through business incubators, modern laboratory and research and development facilities, specialist consultancy, among others in the field of obtaining funding, to projects related to innovation or academic entrepreneurship.

The delegation was presented with the WPT Laboratories operating on the premises of the entity, including clean room and the Experimental Department of the WPT, within which a CO₂ extraction system using an extractor.



Photo 2: Regions4PerMed – Wrocław Technology Park S.A.- Laboratories operating on the premises of the entity, including clean room

Experimental Department of Wrocław Technology Park SA

This is a unique, technologically advanced production installation on a national scale. Tailored to the needs of the life science industry, especially the food, dietary supplements and bioactive preparations sector. The specialized installation located in the Experimental Plant is used for technology testing, up-scaling, verification of assumptions and optimization of production processes. It enables the implementation of innovative solutions, research and development, technology transfer, part or entire production process. The installation consists of 16 production modules on a semi-industrial scale, equipped with high-class devices that enable even complex and advanced processes, such as: extraction in supercritical conditions, electropasteurization, microencapsulation, ultrafiltration, vacuum evaporation or various types of chemical extractions. One of the biggest advantages of the Experimental Plant is not so much the variety of devices available in it as such, but the ability to flexibly configure them with each other. The modules that make up the installation can be combined with each other in any order. Thanks to this, testing and implementing innovations is even faster and easier. The Experimental Plant, by decision of the State Poviats Sanitary Inspector in Wrocław, became an approved production plant and an entity entered in the Register of plants subject to official control of the State Sanitary Inspection. He obtained a positive decision of the District Veterinary Officer in Wrocław regarding the approval of the plant and the granting of a veterinary identification number. The Experimental Plant operates in accordance with the applicable quality control systems, including the Hazard Analysis and Critical Control Points (HACCP) System and Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP) standards. It is a guarantee of safety and quality of the services provided, especially for customers who want to turn their ideas and research results into market products.



Photo 3: Regions4PerMed – Wrocław Technology Park S.A.- supercritical extraction system.

Laboratories and prototype workshops of Wrocław Technology Park S.A.

A part of the WTP's comprehensive technological base for business is the Chemical and Bioengineering Laboratories Complex comprising 12 modern laboratories and prototype workshops equipped with high-class equipment. They create a technologically advanced infrastructure, thanks to which research is



possible, and which allows changing innovative ideas into products that can compete on global markets. Among them:

- a) **Laboratory and prototyping room for chemistry and biotechnology** - specializing in the analysis of i.a. for the food, cosmetic and pharmaceutical industries. Its facilities enable conducting a number of laboratory works - from basic work, through development and implementation research, to production;
- b) **Laboratory and prototyping room for material and biomedical engineering** - the infrastructure available in the laboratory enables research and development in the field of biophysics (including nano- molecular aggregates) and activities focusing on the development of new diagnostic devices, e.g. based on the analysis of sound waves. The laboratory equipment includes photo bioreactors designed at the WTP for biotechnological breeding, intended for the extraction of active substances, e.g. from algae.
- c) **Laboratory for scaling chemical processes** - the infrastructure available in the laboratory enables optimization and transition of organic synthesis processes from strictly laboratory to semi-industrial scale. The multi-module chemical synthesis laboratory, after appropriate configuration, allows it to be used in various manufacturing processes.
- d) **Microbiological laboratory** - specializes in providing research services and performing microbiological analyzes of raw materials, products and formulations at every stage of their development and production. Its offer is dedicated especially to the food and cosmetics industry. A wide portfolio of tests allows you to effectively verify the quality in terms of microbiological parameters and identify potential threats to the safety of food, feed, dietary supplements and cosmetics. The laboratory ensures a high level of research, using appropriate normative research methods, modern equipment and standardized procedures, in accordance with GLP standards.
- e) **Drug development technology laboratory** - the laboratory's infrastructure is intended for conducting research and development works aimed at developing and testing innovative biological drugs. The laboratories include laboratories for research in the field of molecular biology and protein imaging. The laboratory also includes genetic and cell laboratories and a large chemical laboratory equipped with 16 top-class fume cupboards.
- f) **Material properties laboratory** - enables conducting research and physicochemical tests on the material properties of raw materials and products. Its special competence is to issue opinions on the basis of the prepared characteristics.
- g) **Laboratory of optics, photonics and metrology** - specializing in photometric research of light sources, energy efficiency of photovoltaic cells and metrological measurements, including linear and angular measurements of shape geometry, length, angles or diameter, with particular emphasis on large-size devices (optical scanning) of models physical 3D.
- h) **Laboratory of cryogenics and gas technology** - its equipment makes it possible to perform research and development works and prototype cryogenic elements and systems. It also enables the development of cryogenic insulation and modular transmission, storage and distribution systems for liquefied gases.
- i) **Laboratory of electronics, mechatronics and spintronics** - enables testing and diagnostics of electronic components or components, as well as production of printed circuit boards (PCBs). It is equipped with devices enabling manual or automatic assembly of electronic components on printed circuit boards in the through-hole (THT) or surface mounting (SMT) technologies. The entire production process can be carried out in it, from the production of the printed circuit board to the assembly of components on it. Importantly, it can be implemented on a different scale - the production line located in the laboratory is industrial, which allows for mass production of electronic components. WPT also enables the execution of smaller orders, e.g. production of product prototypes or their test batches. It is focused on cooperation with students and production of electronic components for the needs of their academic projects.



- j) **Laboratory and Mechanical Prototyping Room** - the main area of the workshop's activity is the optimization of construction, manufacturing and machining processes. This cycle covers the time from the moment of design (CAD-CAM), through the creation of a virtual model (3D computer visualization), to the digital transfer of this model to automated machining devices and the production of a physical prototype with minimized expenditure of time, energy and materials.
- k) **Destructive testing laboratory** - is equipped with a high-energy, accelerator system for industrial radiography that allows x-raying of large elements (up to 500 mm of steel thickness) in order to observe their internal structure. It can be used to test machine parts and structures, as well as ready, integrated devices or their subassemblies - the so-called assembly imaging.
- l) **IT laboratory** - including a data processing center ensuring high availability of IT services. Thanks to the autonomy in terms of production and delivery of media - power and chilled water - from its own tri-generation node, optimal environmental conditions are maintained in it. Optimum operation of the center is ensured by advanced infrastructure, including: two-way power supply with one of the tracks being powered by an uninterruptible power supply (UPS) and maintaining air humidity parameters. Modern fire protection, access control, monitoring and burglar alarm systems, integrated as part of the internal BMS management system, guarantee the security of the center and the data collected in it.

BIOTTS S.A

A Polish biotechnology company developing proprietary carriers and drug formulas in the field of oncology and diabetology. Based on unique production technologies, a new approach to the processes of combining substances and knowledge, BIOTTS SA has developed a breakthrough technology of the universal transdermal therapeutic system MTC-Y (Multifunctional Transdermal Carrier-Y). The properties of the carrier increase the bioavailability of active substances several times, enabling them to penetrate through the skin into soft tissues and bones. The carrier can be easily modified to achieve targeted effects in diseased tissues. Thanks to the system, it is possible to reduce the therapeutic dose of the drug, while maintaining its original effect and at the same time weakening the side effects. The system also enables the transport of one to a dozen or so active substances, thanks to which it is possible to design multi-ingredient drugs. BIOTTS SA is involved in the development of new methods of delivering biologically medicinal products, such as small molecules, proteins, antibodies and peptides, in order to ensure effective and safe therapy for patients. The company conducts a number of research projects aimed at developing an effective formulation of active medicinal products for patients with various diseases, such as cancer or metabolic diseases. After presenting the case study, the discussion on cooperation between organizations and the reasons why biotech companies are looking for partners outside the EU continued.

WPD Pharmaceuticals Ltd.

A Polish biotechnology company focusing on the development of biological and chemical molecules involved in targeted therapy for brain glioma and other tumors of the central nervous system. WPD Pharmaceuticals Ltd. is a company operating in the field of research and development in the field of PM, specializes in the development of therapies tailored to the individual needs of patients and is involved in the development of new diagnostic and therapeutic methods. WPD Pharmaceuticals Ltd. conducts a number of research projects aimed at developing effective and safe therapies for patients with various diseases, such as cancer. The President of the Management Board of WPD Pharmaceutical Mariusz



Olejniczak presented both the company and its approach to cooperation in the development of medicinal products (ecodevelopment) in the open innovation paradigm. After presenting the case studies there was a discussion on cooperation between organizations and the reasons why biotechnology companies are looking for partners outside the EU.

VASA THERAPEUTICS Ltd.

A private biotech company committed to discovering and developing best-in-class drugs for the treatment of heart, peripheral arterial disease, scarring and other vascular diseases. Aimed at meeting medical needs for the development and commercialization of drugs and therapeutics for the treatment of cardiovascular and other vascular related conditions and conditions such as PAD and sarcopenia. Vasa has three active preclinical programs: two small molecule programs focusing on the treatment of cardiovascular diseases (CVD) and one peptide therapy program aiming to extract a new treatment for peripheral diseases (PAD) and sarcopenia. In Vasa Therapeutics, the entire drug discovery process begins and ends with our state-of-the-art therapeutic chemistry and design care. Our process integrates everything from the strategic control of viable devices that are effective to the design and small molecule or peptide therapeutics that are segregated through our internal drug discovery testing funnel and our network of software partnerships with contract research organisations (CRO).

AMPLICON Ltd.

Polish company from the biotechnology industry, focused on genetic tests detecting celiac disease - celiac disease, caffeine or folic acid metabolism disorders, fructose and lactose intolerance, tendency to be overweight, as well as sports predispositions. Conducting DNA tests for breast or ovarian cancer. Offering diagnostic sets of the AmpliTest and AmpliSNiP series, which enable the diagnosis of infectious diseases - both viral and bacterial, as well as parasitic, enabling the analysis of mutations or polymorphisms. The company develops and produces modern genetic technologies, such as DNA and RNA sequencing, which support scientific research and the development of new therapies. Amplicon is committed to developing innovative genetic solutions to improve people's quality of life. As part of the presentation, examples of cooperation between a company providing services with science and partners were presented.

Regions4PerMed network dinner

The day ended with the Regions4PerMed Networking Dinner at the Radisson Blue Hotel in Wrocław. This gave a unique opportunity for a substantive discussion of the members of the Regions4PerMed project consortium and invited guests - participants of regional workshops. To create a good atmosphere for conversation, a separate room has been reserved. As part of the evening meeting on February 2, 2023, Phd Agnieszka Czyżewska-Buczyńska, a representative of WPD Pharmaceuticals Ltd., presented the concept of implementing PM into practice in the context of the regulatory environment of the Lower Silesian Voivodeship. The main points of the presentation concerned innovation as the main driver of the development of PM and the challenges that arise in implementing the results of PM in health care systems, with particular emphasis on the Lower Silesian. The next point describes the regional conditions of PM and personal health transformation in the health care system, with an emphasis not only on the



Lower Silesian, but also on Poland as the whole country. It was emphasized that innovation is not more important than in the context of human health. But the health innovation system – the very process by which new drugs, vaccines and diagnostics are produced – suffers from declining productivity and rising costs. Health innovation is an interactive and distributed process that includes five main phases: 1. identification of needs, 2. research and development, 3. commercialization, 4. delivery, 5. diffusion. It has been pointed out that these stages are increasingly understood as circular, iterative and highly interconnected - in contrast to the traditional notion of a step-by-step linear process so often inherent in politics. Health innovation is closely linked to the provision, adoption and use of new treatments: feedback from buyers, suppliers and patients is essential to shape the innovation process. Feedback mechanisms are built into the entire innovation cycle and are a source of modification. It was noted that the main feedback trigger is patient education and empowerment, closely related to physicians responsible for maintaining the patient in a personalized healthcare system, accurate creation and implementation of dedicated procedures and processes. The main elements considered in this process of transition from traditional medicine to personalized health are not only patient empowerment, but also providing the appropriate infrastructure to provide access to personalized treatment, building knowledge and awareness and building an information system. At the heart of these processes is a real value for the patient, which also affects the health care system and the entire society. From the perspective of the Lower Silesia region, the biggest challenge is the cost of implementing PM. Taking into account the speaker's experience, a professional in R&D management and clinical trials management, the biggest challenge is the up to 73% funding gap in the process of developing new drugs, which is identified at the clinical trial stage, with a maximum in phase III clinical trials. Throughout the biologics development process, this funding gap can be as high as 90%. It was emphasized that another big challenge is to think about new, innovative drug production in accordance with GMP standards, not only for commercial purposes, but also for the needs of clinical trials. A huge gap in the availability of manufacturers of pharmaceutical active ingredients (API) and medicinal products (DP) was indicated, not only in Lower Silesia, but also in the country. It was pointed out that there are plants producing not only chemical drugs and even Advanced Therapy Medicine (ATMP) products for cell therapy, but this is also not enough to meet regional and national needs in the field of PM and personalized health. The main point of this innovative PM is the lack of or very limited access to free scientific advice, especially at the clinical trial application (CTA) stage, and the lack of unified standards of care for PM. There have been many discussions with our Polish Regulatory Authority (RA) and it seems that this issue will be resolved in the near future, in parallel with the implementation of the new Clinical Trials Regulation (CTR).

Next, the Polish national and regional conditions affecting the implementation of PM in the health care system are presented on the example of glioblastoma multiforme (GBM), the most dangerous brain tumor. There are different therapeutic options for patients with GBM, depending on the stage of the disease, molecular profile and clinical characteristics. But ultimately, as it is still an incurable disease, clinical trials are always the preferred option for these patients. Several different approaches to clinical trials are currently being developed, and implementing any new approach to the clinic, even in the early stages of clinical trials, is a challenge. One innovative drug delivery technique is convection-assisted drug delivery (CED) directly to the brain using special catheters. Due to the blood-brain barrier, it is sometimes the only way to reach cancer cells, especially with a biological compound, e.g. antibody-drug conjugate (ADC). But to do this, specialized equipment must be available, for example a Magnetic Resonance Imaging (MRI) with navigation and life imaging to see how the tumor is coated with the drug, which can be seen during an infusion that can last for hours).



It was emphasized that in Poland there is a centralized clinical trial approval procedure responsible for RA. It is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The average time to obtain approval for a clinical trial was approximately 90 days, depending on the product and the need for additional expertise. From January 31, 2023, the situation has changed because the new Clinical Trials Regulation (CTR) has entered into force. This means that starting from January 31, 2023, each new clinical trial will have to be registered with the EMA for central assessment by the CITIS system, the same for every EU Member State. Implementation of the new regulation takes place on the basis of internal implementing acts of each EU Member State and there may be some differences, but in general terms of assessment and approval will be standardized. This should eliminate the differences that may have been observed previously in the requirements and timing of the CTA assessment and approval process between different EU countries. For ongoing clinical trials, there is a 3-year transition period, which means that all of these trials, if not completed, will have to be registered with CITIS by January 31, 2025.

The next part of the presentation describes the possibilities of financing at the regional, national and European level in order to eliminate this financial gap in the development of innovation. To meet all needs, Poland, under the auspices of the Medical Research Agency, has developed the National Biomedical Sector Development Plan for 2022-2031, which also includes PM, ATMP and many others to be supported by the Polish government as priorities in the development of the Polish economy. It would not be possible without various associations supporting the development of the biomedical sector in Lower Silesia and Poland. These include such associations as: BioInMed, BioForum or INFARMA - the voice of the Union of Employers of Innovative Pharmaceutical Companies and various groups of patient advocates. Patient associations in Poland are among the most important in sharing knowledge about PM and personalized health with patients, as well as in building subjectivity and trust in each unique process that the patient must face on a daily basis.

At the end of the presentation, the role of the Agency for Health Technology Assessment and Tariff System was presented. This agency should be included in the process of implementing PM in the health care system in Lower Silesia. It is a centralized consultative and advisory unit with legal personality, supervised by the Minister of Health. The role of the Agency is to support the Minister of Health in the decision-making process regarding the financing of drugs and other technologies in the health care system. To this end, health technology assessment (HTA) is used in a way that is: reproducible; transparent; in a specific methodological standard; based on evidence and provides the Ministry of Health with data and information supporting the process of making reimbursement decisions for the above-mentioned issues. Health services and reduces the area of uncertainty associated with these decisions. It was pointed out that the role of the Agency is also to initiate, support and conduct analyzes, and research and development works in the field of health technology assessment, setting tariffs and assessing the basic requirements for the provision of health services. This was the starting point for further discussion, which focused on the financing of clinical trials and the financing of procedures by the national health system. The guests pointed to the existing differences in the reimbursement system between regions. Moreover, they all agreed that PM requires huge investments. Developing sustainable lighthouse projects and developing funds/frameworks to sustain successful projects is crucial at the moment, as it is very common for projects to be discontinued after the initial funding period. On the other hand, all agreed that there is a strong need to establish a common structure for financing activities and implementation of PM to enable continuous development in this field in terms of standardized processes and procedures for personalized health that can be implemented in the health system in the



regions. It is also important to reform the health care system, change the systemic approach and dialogue with public entities and HTA agencies, as well as change the management through appropriate financial incentives. However, this is a long-term action and difficult to achieve.



Photo 3: Regions4PerMed – network dinner.

After the presentation, the conversation quickly turned to supporting activities and models that support regional development. Based on the perception of the Lower Silesian ecosystem, the great need to improve access to finance and the lack of venture capital for PH and PM were highlighted as slowing down and limiting interregional coordination efforts for the use of PM and PH in European regions, in particular for the development of SMEs. The high degree of complexity of product development and market regulation in this area make it high-risk and time-consuming. The creation of a dedicated regional venture fund for life sciences and health technology start-ups was endorsed as a useful approach to support the establishment and development of industry to attract more external investment.

The region of Lower Silesia has been confirmed to benefit from a clear regional strategic focus in R&D and investment policy as it increases visibility and helps to increase synergies in the region when supported by the right policy. Participants noted that over the last two decades, the Lower Silesian region has intensified its activities in the field of developing initiatives aimed at the PH and PM area, which translated into the perception of entities in this ecosystem throughout the country and on the international arena. It was underlined that Policy instruments to develop and strengthen interdisciplinary cooperation can be an effective tool for this purpose.

It was recognized that the factor determining the acceleration of activities in the area of personalization in medicine is the increase in the number of clinical trials initiated by (academic) researchers, especially in the case of niche indications with limited profit potential for pharmaceutical companies or to tailor therapies that can reduce corporate profits by improving patient stratification and treatment regimens. The cost-intensive nature of the clinical trial was confirmed, indicating that the mechanisms for financing academic research and the EU funds obtained are often insufficient, because they do not allow for the full conduct of clinical trials and do not take into account economic fluctuations dictated by the volatility of the geopolitical environment. From a systemic perspective, it has been noted that in the EU many

regulations are made at the high policy level while interpretation takes place at the lower levels, potentially leading to a diverse interpretation landscape and regulatory fragmentation. For industry, especially for SMEs, this is a serious problem as it leads to regional and national disparities across the EU. This makes it cumbersome, slow and costly to market regulated products in the EU, creating a barrier to industry development. In comparison, regulations and their interpretation in the US takes place at a higher level, creating a more uniform, consistent and predictable regulatory environment. According to participants, regulatory shortcomings in the EU are compounded by a perceived shortage of staff in regional authorities in some regions, resulting in slowing down processes and a loss of innovation capacity in individual regions, but also across the EU. Regulatory fragmentation favors large companies while at the same time disadvantages SMEs as large companies tend to have the capacity and funding to better manage fragmentation.

Clinical Research Center of the Medical University of Wrocław

The Wrocław Medical University Support Center for Clinical Trials was presented on the third day of the In-Situ visit of Regions4PerMed Project. It is a university-wide unit that provides comprehensive, academic support in the field of planning, coordination and management of clinical trials. The overriding goal of the unit is to streamline, improve the quality and intensify activities related to clinical trials at the Medical University of Wrocław. The Center for Clinical Trials is the place where science is combined with care for the patient. Clinical trials are an important area for the development strategy of the Wrocław Medical University. In recent years, intensive efforts have been made to conduct as many such studies as possible, especially those initiated by scientists, the results of which will directly translate into clinical practice and patients' health. The Wrocław Center is the seventh such center in Poland. They form the Polish Clinical Trials Network, which is planned to gradually expand. Ultimately, the network will consist of 20 centers with uniform standards and providing Polish patients with access to innovative therapies. After creating this network, Poland really has a chance to become a leader in Central and Eastern Europe when it comes to clinical trials.

The Early Phases Center will be used to conduct clinical trials evaluating the safety and effectiveness of modern therapies at an early stage of their development, e.g., first-in-human studies, bioequivalence studies, dose escalation studies, drug interactions, proof-of-concept studies, studies requiring close pharmacokinetic/pharmacodynamic monitoring. The launch of the Early Phases Center will enable the translation of laboratory discoveries into clinical activities with a direct impact on healthcare.

The University Clinical Research Center currently conducts mainly non-commercial clinical trials, in which the Medical University of Warsaw acts as a sponsor or a research unit commissioned by the sponsor Academic Research Organization (ARO). Currently, 10 non-commercial studies are being carried out in the field of cardiology, oncology and hematology. 5 of them are financed by the Medical Research Agency. In addition, the Center is involved in training new adepts of clinical trials. In partnership with the Medical Research Agency and the Association for Good Clinical Trials Practice in Poland, he conducts postgraduate studies "Non-Commercial Clinical Trials - design, implementation and management". These studies are part of the project "Academy of Clinical Research - development of competences of research teams in medical entities providing hospital services and physicians employed in primary health care facilities."

Non-commercial clinical trials conducted by University Clinical Research Support Center:

International Cooperative Treatment Protocol for Children and Adolescents With Lymphoblastic Lymphoma
(LBL 2018)



Effect of INtravenous FERRic carboxymaltose on mortality and cardiovascular morbidity, and quality of life in iron deficient patients with recent myocardial infarCTion (INFERRCT)

Effects of Calcium Electroporation, Electrochemotherapy, and Irreversible Electroporation on Quality of Life and Progression- Free Survival in Patients With Pancreatic Cancer (IREC)

Development of an optimal strategy for the production and administration of CAR-T lymphocytes in adults and children with B-cell nonHodgkin lymphomas and acute lymphoblastic leukemia

Multicentre, open label study to evaluate safety and efficacy of Viral Specific T-lymphocytes (VST) in treatment of refractory viral infections in patients after allogeneic hematopoietic stem cell transplantation (ALLOVISTA)

Secondary prEvention of CardiovascUlar disease in the Elderly trial (SECURE)

A multi-center randomized, placebo-controlled trial of mirabegron, a new beta3-adrenergic receptor agonist on left ventricular mass and diastolic function in patients with structural heart disease (BETA 3_LVH)

Phase I/II Clinical Trial of Autologous Hematopoietic Stem Cell Gene Therapy in RAG1-Deficient Severe Combined Immunodeficiency (RECOMB)

International Study for Treatment of Standard Risk Childhood Relapsed ALL 2010 (IntreAll SR 2010)

International Study for Treatment of High Risk Childhood Relapsed ALL 2010 (IntreAll HR 2010)

Non-commercial clinical trial to confirm safety and efficacy of phage therapy in the treatment of chronic sinusitis (RHINOPHAGE)

The discussion concerned the following issues:

- How to coordinate activities in the case of cooperation with other Centers,
- In the case of cancer patients participating in Clinical Trials, it was found that they were more willing to participate,

After the first treatment, are patients monitored - How is the Centre organized?

GLUCOACTIV Ltd.

A Polish company that creates solutions in the field of modern medicine, focusing on non-invasive measurement of not only blood glucose, but also other substances such as cholesterol, hemoglobin, hydration and many others. Involved in innovative investments and breakthrough technologies in the healthcare industry. During the meeting, particular attention was paid to the scale of the problem in diagnosing diabetes (10% of the world's population in developed countries are people with diabetes and up to 20% are still undiagnosed, the number of deaths per year - 3.7 million people) and the method of monitoring glucose levels (strip glucose meters – invasive method) indicating that the current solutions are painful for the patient and often lead to his resignation from monitoring the disease, despite the awareness that regular glucose control is necessary for diagnosis and proper management of the patient. The presented solution is a non-invasive method using laser light interacting directly with glucose molecules. The received signal after analysis provides information about the patient's blood sugar level. Signals appearing on the market about work on a new version of smartwatches with solutions for non-invasive glycemic monitoring were indicated (no equipment allowing for such a measurement has been presented on the market for at least 5 years). The company presented a table-top device " GlucoStation" for measuring blood glucose levels, indicating that the measurement with its use is fully non-invasive and painless. The device is dedicated for home use, in nursing homes in public facilities. As part of the medical experiment, the device was tested, which confirmed that the " GlucoStation " table-top device is safe for patients and has a sufficiently high correlation with the most accurate glucose measurement available on the market - a laboratory test (uncertainty level - 20%). Currently, the company plans to use the acquired knowledge and experience to create a device for measuring biomarkers of the human body's sweat health. The biomarkers in this study would be cortisol, creatinine, lactic acid, urea pH, vitamin C, iron,



calcium and zinc. As emphasized, this device will be a non-invasive solution that will carry out the diagnostic procedure in a short time. During the discussion, it was pointed out:

- a) no restrictions on the identification of substances using the proposed method,
- b) the fact that work is being carried out on a version of the wearable device equipped with a battery that allows for 24-hour full use of the device,
- c) carrying out further work necessary to certify the device (striving to reduce the uncertainty level below 15%).

MultiMedic POINT

A technology company that provides consulting and design services in the field of IT. Specializing in providing telemedicine solutions. With many years of experience and ready solutions in the field of telecare and telemedicine. The presented mediGOAT telemedicine platform monitors and controls the patient's health and physical parameters. The Telemedicine Platform includes an input module to which are connected monitoring devices (CGM/FGM, Glucometers, SmartPen, Insulin Pump) and a module supporting the Health (Apple iOS) and Google Fit/Health (Android) applications, The mobile application collects, stores and analyzes data from devices and exchanges information with medical entities and doctors. The Communication Portal is used to exchange patient information with the doctor, secure login and data backup. The mediGOAT application works on the iOS and Android platforms. The system is intended for doctors, medical entities (OPZ), Social Care and Welfare Centers, Insurers, Enterprises and is a dedicated solution for diabetology. It monitors the patient's blood glucose level, the dosage of various types of insulin, the dosage of drugs, meals, physical activity and other parameters - e.g., blood pressure, weight. During the discussion it was pointed the security issue of data on mobile device



4 Conclusions

The in-situ visit to the site allowed for an in-depth presentation of the Lower Silesian personalisation in the area of transfer of scientific and research solutions for health care. Feedback from the participants of the visit (Annex C, feedback questionnaires) indicates a positive reception of the form and content of the meeting by the participants. The meeting confirmed that tools and mechanisms for creating and introducing innovative concepts in the field of PM are being developed within the Lower Silesian ecosystem using technical resources and support for enterprises from the business environment unit - WPT SA. carrier of the region's development, but also using the scientific potential, know-how and creativity of entrepreneurs. It is a kind of bridge between entities focused on creating new solutions in the field of PM and university clinics, hospitals, polytechnics and numerous public and private research institutes operating in Lower Silesia. The Lower Silesian PM and PH ecosystem is characterized by a strong academic and scientific base and a growing number of SMEs. The technical and scientific support provided is a factor supporting the development and transfer of scientific solutions to the industry. It was emphasized that innovations are the main driver of the development of PM and the challenges that arise in implementing the results of PM in healthcare systems. It pointed out that the health innovation system - the very process by which new drugs, vaccines and diagnostics are produced - suffers from falling productivity and rising costs. It underlined that health innovation is closely linked to the provision, adoption and use of new treatments: feedback from buyers, suppliers and patients is essential to shape the innovation process. Feedback mechanisms are built into the entire innovation cycle and are a source of modification. It was noted that the main feedback trigger is patient education and empowerment, closely related to physicians responsible for maintaining the patient in a personalized healthcare system, accurate creation and implementation of dedicated procedures and processes. The main elements considered in this process of transition from traditional medicine to personalized health are not only patient empowerment, but also the provision of the appropriate infrastructure to provide access to personalized treatment, building knowledge and awareness, and building an information system. Based on the perception of the Lower Silesian ecosystem, the great need to improve access to finance and the lack of venture capital for PH and PM were highlighted as slowing down and limiting inter-regional coordination efforts for the use of PM and PH in European regions, in particular for the development of SMEs. As a countermeasure, diversification of sources of financing activities in these areas was indicated in order to reduce risk and achieve better results (raising financial capital on markets outside the EU).

It was recognized that the high degree of complexity of product development and market regulation in this area made it high-risk and time-consuming. The creation of a dedicated regional venture fund for life sciences and health technology start-ups was endorsed as a useful approach to support the establishment and development of industry in order to attract more external investment. From a systemic perspective, it has been noted that in the EU many regulations are made at the high policy level while interpretation takes place at the lower levels, potentially leading to a diverse interpretation landscape and regulatory fragmentation. For industry, especially for SMEs, this is a serious problem as it leads to regional and national disparities across the EU. Overall, the dinner attendees agreed that PM and PH have made significant progress over the past decade. Future progress is determined by a truly interdisciplinary approach, an appropriate data infrastructure, policies to facilitate innovation, administrative and funding support, i.e., in areas where regions can shape the appropriate ecosystem by taking supportive actions. Further targeted efforts at the higher policy level are also needed to reduce regulatory fragmentation in the EU to make market access strategies more predictable and manageable, especially for SMEs. Efforts to achieve this goal must be carefully planned so as not to create new constraints.



Appendix A Site visit by participants

Participants of the in situ visit

Participant	Function	Organization	Position
Claudia Mariut	Coordinator of Regions4PerMed	Fondazione Toscana Life Sciences, Italy	Project Manager
Phd Eva-Maria Stegemann	Partner Regions4PerMed	Saxon State Ministry for Science, Culture and Tourism	Policy Officer
Justyna Jureczek	Partner Regions4PerMed	Wroclaw University Medical , Poland	Clinical Research Coordinator at the Clinical Research Center of the Medical University of Wrocław
Phd Joanna Misztal-Dadacz	Partner Regions4PerMed	Lower Silesian Marshal's Office, Poland	Head of the Public Health Team (Department of Health)
Aldona Iwasieczko	Partner Regions4PerMed	Lower Silesian Marshal's Office, Poland	Chief Specialist of the Public Health Team (Department of Health)
Marcello De Amico	Partner Regions4PerMed	Fondazione Regionale per La Ricerca Biomedica, Italy	Project Manager
Phd Marta Duda-Sikula	Partner Regions4PerMed	Wroclaw Medical University, Poland	Clinical Research Coordinator at the Clinical Research Center of the Medical University of Wrocław
Phd Letizia Pontoriero	Coordinator of Regions4PerMed	Fondazione Toscana Life Sciences, Italy	Scientific Project Manager
Dorota Stefanicka-Wojtas	Partner Regions4PerMed	Wroclaw Medical University, Poland	Clinical Research Coordinator at the Clinical Research Center of the Medical University of Wrocław
Alejandro Vázquez Pombo	Partner Regions4PerMed	Axencia Galega de Coñecemento en Saúde, Spain	Project Manager
Anna Pawlitzak	Partner Regions4PerMed	Lower Silesian Marshal's Office, Poland	Chief Specialist of the Public Health Team (Department of Health)
Renata Sierżant	Guest		
Phd Antoni Zwiefka	Guest		



Additional guests for the networking dinner

- Marcin Olejniczak, (President of WPD Pharmaceuticals Ltd.)
- Phd Agnieszka Czyżewska-Buczyńska, (representative of WPD Pharmaceuticals Ltd.)
- Anna Bednarska, (representative of Wrocław Technology Park SA)
- Paweł Myszczyński, (representative of Wrocław Technology Park SA)
- Konrad Krajewski (representative of BIOTTS SA)
- Phd Małgorzata Guzewicz (expert in clinical trials of BIOTTS SA)
- Janusz Piechota (representative of AMPLIKON Ltd.)



Appendix B Participant Feedback - Survey

(based on scanned documents, hence the formatting is not optimal in all cases)

Partner & Participant Questionnaire REGIONS4PERMED Wrocław, 1-3 February 2023

<p>1. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?</p>
<p><u>Day Programme 02.02.2023</u></p>
<p>In my opinion, I found that all the facilities and laboratories in the Wrocław Technology Park were very advanced. The impression was that the hub, where it is possible to find many companies, is an ideal environment to invest optimally and come up with new ideas dedicated to scientific experiments.</p>
<p><u>Networking Dinner Regions4PerMed 02.02.2023</u></p>
<p>During the dinner, stakeholders expounded on relevant issues dealt with by some European projects (Interreg Baltic Sea Region), in which WTP is a partner (such as the regulation of BICs), for which it is important to establish continuous dialogue and discussion with public and private actors involved in scientific research.</p>
<p><u>Day Programme 03.02.2023</u></p>
<p>The visit held at Wrocław Medical University provided an insight into clinical trials conducted by university researchers. It was also an opportunity to learn about some instrumentation, designed by a start-up company (such as GLUCO ACTIVE Ltd), useful for monitoring levels of glucose and other substances in the blood. Due to early return, it was not possible for me to visit the Cancer center and the Multi Medic Point on Diabetes, which would surely have been interesting to see.</p>
<p>2. If you compare what you know about your own regional PM innovation ecosystem to the components of the Lower Silesia PM innovation system that were presented to you - are there notable difference in set up and approaches? Please describe.</p>
<p>The perception is that the Wrocław Technology Park, together with the Lower Silesian components and the University of Wrocław collaborate in full synergy with the ecosystem of private companies and start-ups, producing such enviable results in terms of research.</p> <p>This full collaboration is also beneficial because it creates new and exciting job and personal growth opportunities for students/researchers and especially for the city, which is currently growing at the economic level.</p> <p>Considering the differences between the regions, it is difficult to make a comparison.</p>
<p>3. Were there take-home messages /models that you consider transferable and important for other European regions with an interest in PM? Please share below.</p>
<p>N/A</p>
<p>4. Was there any part of the programme that you found particularly beneficial?</p>
<p>The visit to the Wrocław Technology Park was very interesting as we could see the excellent use of resources in creating modern and many buildings, suitable for hosting research and innovation realities that will bring great benefits to the research ecosystem in Poland.</p>
<p>5. Please share with us your thoughts, what could have been done better?</p>
<p>N/A</p>
<p>6. Any other comments?</p>
<p>N/A</p>



**Partner & Participant
Questionnaire REGIONS4PERMED
Wrocław, 1-3 February 2023**

<p>1. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?</p>
<p>Day Programme 02.02.2023</p> <p>The whole programme was very interesting and well structured. It was a true benefit that we could spend time on-site at Wrocław Technology Park, which is quite impressive (the dimensions of the park became obvious to us when our bus first went to the wrong building...). The overview provided about the park was very helpful to understand its full offer: its facilities are very well equipped with 14 different technological laboratories for the use of the tenants. Its close proximity to Wrocław Medical University seems to be an added benefit for both sides. I was especially impressed by the supercritical carbon dioxide extraction liquid chromatography facility which seems to be unique in Poland, and possibly beyond.</p> <p>The corporate presentations were very interesting, technologically, but also in respect to growth and development strategies of the companies, which is highly relevant from the perspective of KA3. Notably, the faster-growing companies were all set up with some connection to North American biotech-ecosystems, whereas the only company that took a more conservative and slow („organic”) approach for its development (Amplicon) did not have such a connection. This observation may be coincidental, but it does match my personal perception that fast growth of European companies are usually connected with an outward-looking approach for financing their growth. To obtain better access for funding, such companies tend to include ecosystems beyond national (and European) boundaries). This may not necessarily be true for a pre-seed, seed or series A funding, but for later funding this seems to be essential for such companies. One company (WPD Pharmaceuticals) is currently quoted on the Canadian Stock Exchange. However, it became also evident from the discussions that the need to obtain financing outside of Europe is posing an extra challenge for the management of such companies.</p>
<p>Networking Dinner Regions4PerMed 02.02.2023</p> <p>The key-note lecture was really interesting. I very much enjoyed the in-depth conversations with representatives from the companies that had presented in the afternoon. I had the impression that founders in the field of PM face similar hurdles irrespective of the region in which their company is located. The importance of the local ecosystem for such companies was described by the company representatives that were present at the dinner. It is important that companies have access to qualified staff, for example experts that have regulatory experience etc. Also, it seemed that some new resources of WMU, notably the University Clinical Research Support Center, are an added value for this ecosystem.</p>
<p>Day Programme 03.02.2023</p> <p>I was, again, very impressed by the different presentations that were shown, especially by the concept of Gluco Active Ltd., which plans to address a critical medical need in the market. Also, the WMU Biobank was very interesting to see, as is the first accredited biobank of Europe. I found it</p>



surprising and noteworthy that the city of Wroclaw is supporting population research which also involves the biobank.

In addition to this, it seems that the Polish Health Research Agency is following a very logic and straightforward approach with their programme to further improve and professionalize clinical research at Polish University(?) Hospitals by setting up dedicated centers for such research with the Polish Clinical Trials Network (PCTN).

2. If you compare what you know about your own regional PH i PM innovation ecosystem to the components of the Lower Silesia PM i PH innovation system that were presented to you - are there notable difference in set up and approaches? Please describe.

The centralized Polish Strategy to professionalize clinical trials with a national programme seems to be a very smart approach to ensure uniform standards and professional exchange between these centers. This is an added value for the Lower Silesian PH and PM ecosystem. It may turn out to be really beneficial for networking between such centers and may important links between different regional ecosystems with Poland. Also, the dimensions and equipment of Wroclaw Technology Pare are impressive. The situation for start-up founders seems to be similar to our region.

3. Where there take-home messages /models that you consider transferable and important for other European regions with an interest in PM and PH? Please share below.

The corporate presentations all touched on the issue of financing: how do PM and PH start-up companies manage to obtain sufficient funding by investors for their high-risk-high-potential development projects to develop products to a highly regulated (and in EU also fragmented) market? It became evident that all companies planning for an ambitious growth strategy have already accessed or work on accessing the North American capital markets. This is a valid approach, however it places an additional burden on corporate management and it encompasses the risk that eventually the value that is generated by these companies in Europe is harvested outside of EU (by North American investors).

I take from this that there is some need for action to improve the financing ecosystem for such companies in Europe. This seems to be important to be able to stay competitive to US counterparts, who have a much more straightforward access to funding. (Writing this, I do not mean to discredit organic growth strategies that do not require large amount of funding; these may be the basis for a valid and competitive business model - however, later switching such a strategy towards fast growth can be tough, there is a high likelihood that investors will be skeptical and access to capital may be problematic).

The relatively newly created PCTN and the dedicated approach by the Polish Health Research Agency to create a uniform market for clinical trials is a concept that should be further monitored and may be something that could be „imported" by other countries to improve their regional ecosystems for PM and PH. It may also be a good concept for creating additional linkages between these ecosystems and thus to better connect them.

4. Was there any part of the programme that you found particularly beneficial?

Everything was excellent. It was really good to have sufficient time for communication with representatives of the Lower Silesia PM and PH community. It was also very nice to start the in-situ visit with a city tour. This also provided a deeper understanding of the historical challenges that the region underwent - especially in connection to World War II (WWII) and I think that it is very important for European cross-regional interaction to keep this historic background in mind.

5. Please share with us your thoughts, what could have been done better?

I do not think that anything could have been done better! It was really, really well organized and excellent. Maybe the weather, could have been nicer=> next in-situ should take place in spring©.

6. Any other comments?



THANK YOU

**Partner & Participant
Questionnaire REGIONS4PERMED
Wrocław, 1-3 February 2023**

1. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?
Day Programme 02.02.2023
The visit to the Wrocław Technology Park was quite complete. First, it was interesting to see the different presentations to learn more about the park, the activities they carry out and also learn about some of the companies that operate in the park; and later, being able to see in person some of the facilities where they carry out their work and research.
Networking Dinner Regions4PerMed 02.02.2023
I liked the pre-dinner presentation because it allowed people to discuss and talk about the integration of PM and personalized health into the healthcare system over dinner.
Day Programme 03.02.2023
I found the latest visits to the facilities to be particularly interesting, very well explained first-hand by the professionals who worked there. Also check how they kept the results of their work at very low temperatures in the refrigerators.
2. If you compare what you know about your own regional PH i PM innovation ecosystem to the components of the Lower Silesia PM i PH innovation system that were presented to you – are there notable difference in set up and approaches? Please describe.
From what I was able to see, more or less the formation of the Lower Silesia ecosystem and the Galician ecosystem of health knowledge are very similar. Both have a business sector, health research institutes or foundations, and support and knowledge exchange agents. Perhaps the main difference is that the main agent of the Galician ecosystem is the Galician public health service (SERGAS), which is the body of the autonomous administration of Galicia in charge of public health care.
3. Were there take-home messages /models that you consider transferable and important for other European regions with an interest in PM and PH? Please share below.
It may be interesting to share the experience in the assignment and rental of facilities to specialized companies. Also share some of the devices and equipment used in the processes, as well as the cooling processes of the results.
4. Was there any part of the programme that you found particularly beneficial?
Personally, it was interesting to see what the patient rooms were like in the Early Phase Center, where I also found the placement of the windows to be striking in order to see the patients from the corridor with a view of the entire room. In general, it seemed to me that the laboratory facilities of the Wrocław Technology Park were very complete and it is beneficial that they could be rented for a certain time by companies and also that they could be adapted to the needs of each one.
5. Please share with us your thoughts, what could have been done better?
Everything has been very well organized so I can't think of anything to add that could have been done better.
6. Any other comments?
-

